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Attorney Docket No.: August 14, 2003

AMENDMENT TRANSMITTAL

In re the Application of

Pramod N. DESHPANDE et al.

Group Art Unit: 1624

Application No.: 10/035,178

Examiner: M. Berch

Filed: January 4, 2002

For: SYNTHESIS OF CEFTIOFUR INTERMEDIATE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Amendment in the above-identified application.

- ☐ Entitlement to small entity status is hereby asserted.
☐ Small entity status of this application has been established.

The filing fee has been calculated as shown below:

(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN A SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	RATE	ADD'L FEE		RATE	ADD'L FEE
TOTAL CLAIMS	13 MINUS	20	x 9	\$		x 18	\$
INDEP CLAIMS	5 MINUS	3	x 42	\$		x 84	\$ 168
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM			+ 140	\$		+ 280	\$
				\$			\$ 168

- * If the entry in Column 1 is less than the entry in Column 2, write "0" in Column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" in this space (Total or Independent) is the highest number found from the equivalent box in Column 1 of a prior Amendment or the number of claims originally filed.

- ☒ Check No. 145242 in the amount of \$168 is attached. The Commissioner is hereby authorized to charge any other fees that may be required to complete this filing, or to credit any overpayment, to Deposit Account No. 15-0461. Two duplicate copies of this sheet are attached.

Respectfully submitted,

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Jacob A. Doughty
Registration No. 46,671

JAO:WPB:JAD/ldg

Date: August 14, 2003

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Pramod N. DESHPANDE et al.

Group Art Unit: 1624

Application No.: 10/035,178

Examiner: M. Berch

Filed: January 4, 2002

Docket No.: 113299

For: SYNTHESIS OF CEFTIOFUR INTERMEDIATE

EXHIBITS TO RULE 608(b) SHOWING AND RULE 608(b) DECLARATIONS
OF DR. DAS AND MESSRS. DESHPANDE, KHADANGALE, JEYA KUMAR,
SENTHIL KUMAR, MUKUNDAN, PATHAK AND VIVEK

Date: August 14, 2003



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Pramod N. DESHPANDE et al.

Application No.: 10/035,178

Filed: January 4, 2002

For: SYNTHESIS OF CEFTIOFUR INTERMEDIATE

Group Art Unit: 1624

Examiner: M. Berch

Docket No.: 113299

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RULE 608(b) SHOWING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In connection with the accompanying Amendment, this paper and the attached Declarations and Exhibits* demonstrate that applicants are *prima facie* entitled to judgment in an interference relative to the patentee of U.S. Patent No. 6,476,220 B2 (the "U. Kumar et al. patent"). The bases upon which applicants are *prima facie* entitled to the judgment are explained below.

I. INTRODUCTION

In summary, applicants are entitled to judgment because (A) the invention of the proposed Count was made by the applicants before any effective filing date of the U. Kumar et

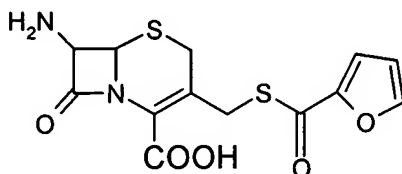
* The documents provided herewith as Exhibits 4-14 to this Showing and the attached Declarations have been redacted to remove references to dates appearing in the documents.

al. patent, (B) the U. Kumar et al. patent "inventors" derived the invention of the proposed Count from the applicants, (C) the U. Kumar et al. patent is invalid under 35 U.S.C. §102(f) because the named inventors did not themselves invent the subject matter sought to be patented, and (D) the U. Kumar et al. patent is invalid for inequitable conduct by at least Mr. Uthira Kumar in knowingly and intentionally swearing to the incorrect inventorship.

II. PROPOSED COUNT

The proposed Count is claim 16 of the above-captioned patent application, and reads as follows:

A process to prepare a cephalosporin compound (Furaca (3-[2-(furylcarbonyl)thiomethyl]-3-cephem-4-carboxylic acid) represented by formula (I),

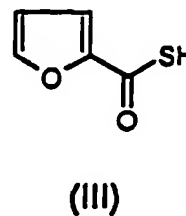
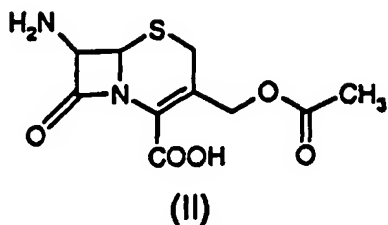


(I)

comprising:

- (a) combining the following components:
 - (i) a catalyst solution of boron trifluoride (BF₃) in an organic solvent or in a mixture of organic solvents,
 - (ii) a solution of 2-thiofuroic acid (furyl-2-carbonylthiol) of the formula (III) in a solvent, and
 - (iii) 7-aminocephalosporanic acid of the formula (II), and

(b) precipitating Furaca (3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid) as a solid.



The following terminology as used and confirmed in the attached Declarations will help simplify the analysis:

Furaca is also known as (3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid), is abbreviated ACF, and has the formula (I) above;

Boron trifluoride has the chemical formula BF_3 ;

2-Thiofuroic acid is also known as furyl-2-carbonylthiol, is abbreviated TFA, and has the formula (III) above;

7-Aminocephalosporanic acid is abbreviated 7-ACA and has the formula (II) above;

Ethyl acetate is abbreviated EtOAc, and is an organic solvent; and

Acetic acid is abbreviated HOAc, and is also an organic solvent.

Thus in simplified format but with the same content, the proposed Count recites a process to prepare furaca (ACF), comprising (a) combining (i) boron trifluoride (BF_3) in an organic solvent or in a mixture of organic solvents, (ii) a solution of 2-thiofuroic acid (TFA) in a solvent, and (iii) 7-ACA, and (b) precipitating furaca (ACF) as a solid.

III. APPLICANTS ARE *PRIMA FACIE* ENTITLED TO JUDGMENT

A. **The Invention of the Proposed Count Was Made by the Applicants Before Any Effective Filing Date of the U. Kumar et al. Patent**

The Declarations of Dr. Das, Mr. Deshpande and Mr. Khadangale, the present inventors, establish that the present inventors had conceived of the invention of the proposed Count and communicated it to others before November 27, 2000, which is the claimed (but not established) priority date of the Kumar et al. patent, and thus well before its U.S. filing date. *See* Declaration of Dr. Das ("Das Dec."), ¶¶ 5-19; Declaration of Mr. Deshpande ("Deshpande Dec."), ¶¶ 5-19; Declaration of Mr. Khadangale ("Khadangale Dec."), ¶¶ 5-10. The Das, Deshpande and Khadangale Declarations also demonstrate that this prior conception satisfied every limitation of the proposed Count. *See* Das Dec., ¶¶ 17, 18; Deshpande Dec., ¶¶ 17, 18; Khadangale Dec., ¶¶ 8, 9. In particular, the Das, Deshpande and Khadangale Declarations demonstrate that the present inventors instructed their assistant chemists to prepare furaca by combining BF_3 in EtOAc and HOAc as a mixture of organic solvents, TFA in a solvent (EtOAc) in which the TFA was prepared, and 7-ACA, and to precipitate the resultant furaca, thereby establishing conception and communication to others of an embodiment of the proposed Count, before November 27, 2000. This prior conception and communication are corroborated by the Declarations of Messrs. Jeya Kumar, Senthil Kumar, Mukandan, Pathak and Vivek. *See* Declaration of Mr. Jeya Kumar ("J. Kumar Declaration"), ¶¶ 5-16; Declaration of Mr. Senthil Kumar ("S. Kumar Dec."), ¶¶ 5-16; Declaration of Mr. Mukandan ("Mukandan Dec."), ¶¶ 5-16; Declaration of Mr. Pathak ("Pathak Dec."), ¶¶ 5-11; Declaration of Mr. Vivek ("Vivek Dec."), ¶ 5.

The Das and Deshpande Declarations further establish that the invention of the proposed Count conceived by the present inventors was reduced to practice at their direction and on their behalf on various occasions before November 27, 2000. *See* Das Dec., ¶¶ 20-85; Deshpande Dec., ¶¶ 20-93. In particular, the Das and Deshpande Declarations establish that the inventors

instructed assistant chemists as to the necessary steps and the manner in which those steps were to be carried out in order to reduce the invention of the proposed Count to practice on their behalf. *See* Das Dec., ¶¶ 8-19; Deshpande Dec., ¶¶ 8-19. The Das and Deshpande Declarations also establish that those assistant chemists, including Messrs. Uthira Kumar, Jeya Kumar, Senthil Kumar and Mukundan, did reduce the invention as described above to practice on behalf of the inventors before November 27, 2000. *See* Das Dec., ¶¶ 20-85; Deshpande Dec., ¶¶ 20-85; Exhibits 6-12. The Das and Deshpande Declarations further demonstrate that this prior reduction to practice satisfied every limitation of the proposed Count. *See* Das Dec., ¶¶ 23, 24, 31-32, 39-40, 47-49, 57-59, 66-68, 80-82; Deshpande Dec., ¶¶ 23, 24, 31-32, 39-40, 47-49, 57-59, 66-68, 80-82. This prior reduction to practice is corroborated by the Jeya Kumar, Senthil Kumar, Mukundan, Pathak and Vivek Declarations. *See* J. Kumar Dec., ¶¶ 5-49; S. Kumar Dec., ¶¶ 5-73; Mukundan Dec., ¶¶ 5-26; Pathak Dec., ¶¶ 8-18; Vivek Dec., ¶ 5.

The Deshpande Declaration establishes that the invention of the proposed Count was further reduced to practice on behalf of the present inventors by their assignee, Orchid Pharmaceuticals and Chemicals Limited ("Orchid"), before November 27, 2000. In particular, the Deshpande Declaration and Exhibit 14 establish that Orchid, by way of its development and production staff under the supervision of Mr. Pathak and Mr. Deshpande again reduced the invention to practice on behalf of the inventors before November 27, 2000. *See* Deshpande Dec., ¶¶ 86-93; Exhibit 14. The Deshpande Declaration also demonstrates that this prior reduction to practice satisfied every limitation of the proposed Count as described above. *See* Deshpande Dec., ¶¶ 88-90. This prior reduction to practice is corroborated by the Pathak Declaration and by Exhibit 14. *See* Pathak Dec., ¶¶ 12-18; Exhibit 14.

Thus, the accompanying evidence establishes that applicants are at least *prima facie* entitled to judgment in the requested interference because the invention of the proposed Count

was made by the applicants (conceived by the applicants and reduced to practice on behalf of the applicants) before any effective filing date of the U. Kumar et al. patent.

**B. The U. Kumar et al. Patent "Inventors" Derived the
Invention of the Proposed Count from the Applicants**

The Declarations of the present inventors establish that the present inventors had conceived of the invention of the proposed Count as detailed above, and communicated it to Mr. Uthira Kumar, one of the named "inventors" of the Kumar et al. patent, before November 27, 2000, which is the claimed (but not established) priority date of the Kumar et al. patent and thus well before its U.S. filing date. *See* Das Dec., ¶¶ 8-19, 20, 26-28, 34-36, 42-54, 61-63, 70-71, 77, 84, 85; Deshpande Dec., ¶¶ 8-19, 20, 26-28, 34-36, 42-54, 61-63, 70-71, 77, 84, 85; Khadangale Dec., ¶¶ 5-10. The Das, Deshpande and Khadangale Declarations demonstrate, in particular, that this prior conception satisfied every limitation of the proposed Count as detailed above, and confirms that Mr. Uthira Kumar understood the communication well enough to carry out the instructions to perform the process of the proposed Count, although he was not sufficiently experienced to generate such an invention himself. *See* Das Dec., ¶¶ 11, 17, 18, 44-53; Deshpande Dec., ¶¶ 11, 17, 18, 44-53; Khadangale Dec., ¶¶ 8, 9. This prior conception and communication are corroborated by the Jeya Kumar; Senthil Kumar, Mukundan, Pathak and Vivek Declarations. *See* J. Kumar Dec., ¶¶ 5-27, 34-36, 43, 44; S. Kumar Dec., ¶¶ 5-17, 23-25, 31-33, 39-51, 58-59, 65, 72, 73; Mukandan Dec., ¶¶ 5-17, 24, 25; Pathak Dec., ¶¶ 8-11; Vivek Dec., ¶ 5. Thus, the inventors of the Kumar et al. patent derived the invention from the present inventors.

Thus, the accompanying evidence establishes that applicants are at least *prima facie* entitled to judgment in the requested interference because the U. Kumar et al. patent "inventors" derived the invention of the proposed Count from the applicants.

**C. The U. Kumar et al. Patent Is Invalid Under
35 U.S.C. §102(f) Because the Named Inventors Did Not
Themselves Invent the Subject Matter Sought to be Patented**

The Declarations of the present inventors establish that the named inventors of the U. Kumar et al. patent did not themselves invent the subject matter sought to be patented. *See* Das Dec., ¶¶ 8-19, 20, 26-28, 34-36, 42-54, 61-63, 70-71, 77, 84, 85; Deshpande Dec., ¶¶ 8-19, 20, 26-28, 34-36, 42-54, 61-63, 70-71, 77, 84, 85; Khadangale Dec., ¶¶ 5-10. The subject matter of all three claims of the U. Kumar et al. patent was communicated to Mr. Uthira Kumar by the present inventors, without any inventive contribution from Mr. Uthira Kumar. Furthermore, the subject matter of those claims appears in all significant respects to be the subject matter that Mr. Uthira Kumar was instructed to carry out by the present inventors. *See* Das Dec., ¶ 52; Deshpande Dec., ¶ 52. To the extent that there are any differences, such differences and the described methods would have been obvious to anyone with ordinary skill in the art of furaca synthesis (e.g., a chemist with a post graduate chemistry degree and some experience in an organic chemistry synthesis laboratory) at the time in view of the instructions provided by the present inventors. These facts are corroborated by the Jeya Kumar; Senthil Kumar, Mukundan, Pathak and Vivek Declarations. *See* J. Kumar Dec., ¶¶ 5-27, 34-36, 43, 44; S. Kumar Dec., ¶¶ 5-17, 23-25, 31-33, 39-51, 58-59, 65, 72, 73; Mukandan Dec., ¶¶ 5-17, 24, 25; Pathak Dec., ¶¶ 8-11; Vivek Dec., ¶ 5.

Nevertheless, the U. Kumar et al. patent names Mr. Uthira Kumar and two others as inventors of the subject matter claimed therein, and does not name any of the present inventors as co-inventors. From the facts established in the accompanying Declarations, it is apparent that Mr. Uthira Kumar and the other two named inventors of the U. Kumar et al. patent obtained all of the claimed subject matter from the present inventors, and did not themselves make any inventive contribution to the claimed subject matter. Even if it is found that they made some

minor contribution to what is claimed (which is not presently apparent), the basic concepts and most of the details of what is claimed were contributed by the present inventors. Thus the U. Kumar et al. patent improperly names the inventors listed therein, and improperly fails to list the present inventors.

Thus, the accompanying evidence establishes that applicants are at least *prima facie* entitled to judgment in the requested interference because the U. Kumar et al. patent is invalid under 35 U.S.C. §102(f) because the named inventors did not themselves invent the subject matter sought to be patented.

D. The U. Kumar et al. Patent Is Invalid for Inequitable Conduct by at least U. Kumar in Knowingly and Intentionally Swearing to the Incorrect Inventorship

The Declarations of the present inventors establish that the named inventors of the U. Kumar et al. patent did not themselves invent the subject matter sought to be patented by them. *See* Das Dec., ¶¶ 8-19, 20, 26-28, 34-36, 42-54, 61-63, 70-71, 77, 84, 85; Deshpande Dec., ¶¶ 8-19, 20, 26-28, 34-36, 42-54, 61-63, 70-71, 77, 84, 85; Khadangale Dec., ¶¶ 5-10. That same evidence further establishes that Mr. Uthira Kumar himself was very aware of the correct inventorship. These facts are corroborated by the Jeya Kumar; Senthil Kumar, Mukundan, Pathak and Vivek Declarations. *See* J. Kumar Dec., ¶¶ 5-27, 34-36, 43, 44; S. Kumar Dec., ¶¶ 5-17, 23-25, 31-33, 39-51, 58-59, 65, 72, 73; Mukundan Dec., ¶¶ 5-17, 24, 25; Pathak Dec., ¶¶ 8-11; Vivek Dec., ¶ 5. However, Mr. Uthira Kumar signed a Declaration submitted to the Patent Office during prosecution of the U. Kumar et al. patent declaring that he and the two named "co-inventors" were the joint inventors of the subject matter claimed in the patent. *See* Exhibit 15.

Incorrect inventorship is grounds for invalidation of a patent under 35 U.S.C. §102(f). Thus, information about incorrect inventorship, both in the inclusion of non-inventors and in the omission of inventors, is *per se* highly material to patentability. Furthermore, Mr. Uthira Kumar

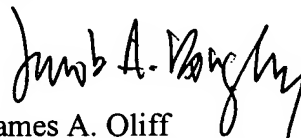
clearly intentionally signed the Declaration misrepresenting the inventorship to the Patent Office, with knowledge of the misrepresentation from his activities at Orchid. Thus, a high level of intent is also established. Balancing the high level of materiality of the misrepresentation and the high level of intent of Mr. Uthira Kumar, it is clear that Mr. Uthira Kumar committed inequitable conduct in misrepresenting the inventorship of the subject matter claimed in the U. Kumar et al. patent to the Patent Office.

Thus, the accompanying evidence establishes that applicants are at least *prima facie* entitled to judgment in the requested interference because the U. Kumar et al. patent is invalid for inequitable conduct by at least Mr. Uthira Kumar.

IV. CONCLUSION

For at least each and all of the above reasons, the accompanying evidence establishes that applicants are at least *prima facie* entitled to judgment in the requested interference.

Respectfully submitted,



James A. Oliff
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William P. Berridge
Registration No. 30,024

Jacob A. Doughty
Registration No. 46,671

JAO:WPB:JAD/hs

Attachments:

Exhibit 1 - Claims	Das Declaration
Exhibit 2 - Assignment	Deshpande Declaration
Exhibit 3 - U.S. Patent No. 6,476,220 B2	Khadangale Declaration
Exhibit 4 - Uthira Kumar Resume	Jeya Kumar Declaration
Exhibit 5 - Uthira Kumar Offer Letter	Senthil Kumar Declaration
Exhibit 6 - Page from Separate Laboratory Notebook	Mukundan Declaration
Exhibit 7 - Page from Separate Laboratory Notebook	Pathak Declaration
Exhibit 8 - Pages from Common Laboratory Notebook	Vivek Declaration
Exhibit 9 - Pages from Common Laboratory Notebook	
Exhibit 10 - Pages from Common Laboratory Notebook	
Exhibit 11 - Pages from Common Laboratory Notebook	
Exhibit 12 - Pages from Common Laboratory Notebook	
Exhibit 13 - Pages from Common Laboratory Notebook	
Exhibit 14 - Batch Processing Record	
Exhibit 15 - Declaration for U. Kumar et al. Patent	

Date: August 14, 2003

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